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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,033	10/22/2001	Patrick C. Kung	YALE-025/02US 306577-2036	9303
58249                      7590                      06/18/2008 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001				
EXAMINER				
BORIN, MICHAEL L				
ART UNIT		PAPER NUMBER		
1631				
MAIL DATE		DELIVERY MODE		
06/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/830,033

**Applicant(s)**

KUNG ET AL.

**Examiner**

Michael Borin

**Art Unit**

1631

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 83, 84, 87 and 88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83, 84, 87, 88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CI)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of Claims**

Response filed 03/26/2008 is acknowledged.

Claims 83,84,87,88 are pending.

### ***Claim Rejections - 35 USC § 103.***

Claims 83,84,87,88 are rejected under 35 U.S.C. 103(a) as obvious over Khwaja et al (US Patent 6113907) in view of Lochardt (US patent 6040138).

The rejection is maintained for the reasons of record and further in view of the following.

The applicant's response seems ambiguous as it is not quite clear what applicant addresses as "biosystem" in various parts of the response. All potential meanings are addressed below.

Applicant seems to argue that method of Khwaja measures activities of individual fractions of St. John's extract while the instant method measures response of a biosystem.

"More importantly, while the Khwaja method is based on measuring series of biological activities of the individual fractions of St. John's Wort extract, the claimed method is based on measuring the biological response of a biosystem" (response, p. 5, lines 9-10)

If applicant's position is that the tested pharmaceutical composition is a biosystem, then it is not supported by the claim language that addresses it not as an entire "biosystem", but a "composition comprises multiple chemical components derived from one or more whole plants or plant parts" - i.e., the same as addressed in Khwaja reference.

If applicant rather means, as it seems from discussion on p. 6, first full paragraph, that the instant composition is multi-component compared to "individual fractions" of Khwaja, then the Khwaja method is not limited to "individual fractions" but addresses testing of full extract as well –see col. 13, lines 59-61. In addition, the individual fractions of Khwaja are not single components, but may comprise a plurality of compounds (see col. 10, lines 7-8), which also reads on the "composition comprising multiple chemical components derived from one or more whole plants or plant parts" as instantly claimed.

Further, if addressing "biosystem" is related to the "biosystem" used in the instant method (i.e., a cell, tissue, or whole organism, as in claim 84), as argued on p. 6, bottom, of the response, then the method of Khwaja clearly addresses use of cells, tissues, or whole organisms in testing the properties of herbal compositions – see col. 24, section 5.4.2 describing use of cell-, tissue-, or whole animal assays. See also col. 23, lines 24-27. furthermore, the reference clearly suggests genomic assaying in cell-based screening – see col. 26, lines 30-34.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571)272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./  
Primary Examiner, Art Unit 1631